*SESSION OF 2015*

## SUPPLEMENTAL NOTE ON HOUSE BILL NO. 2004

As Amended by House Committee on Health and Human Services

### Brief*

HB 2004, as amended, would create the Kansas Right to Try Act, permitting eligible patients to use investigational drugs, biological products, or devices (investigational drugs) not yet approved by the U.S. Federal Drug Administration (FDA). The bill also would include legislative findings and declarations supporting the Act.

The bill would define the following:

- "Eligible patient" as a person who is not being treated as an inpatient in a hospital or recuperation center and who has:
    - A terminal illness, attested to by the patient's treating physician;
    - Considered all treatment options approved by the FDA;
    - Been unable to participate in a clinical trial;
    - Received a recommendation from the patient's treating physician;
    - Given written, informed consent; and
    - Received documentation from the patient's treating physician stating the patient meets the requirements.
- "Investigational drug, biological product, or device" means a drug, biological product, or device that

*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at http://www.kslegislature.org

has successfully completed phase one of an FDA clinical trial, remains under investigation by the FDA, and is not approved for general use;

- "Terminal illness" means a condition that, without life-sustaining procedures, will result in death or a permanent state of unconsciousness;

- "Written, informed consent" means a written document signed by the patient and attested to by the patient's treating physician and a witness; and

- "Physician" means a person licensed to practice medicine and surgery by the Board of Healing Arts.

The bill would require the "written, informed consent" include specific elements that follow:

- Explain the approved products and treatments relevant to the patient's condition;

- Attest to the fact the patient concurs with the treating physician's assessment of the patient's condition;

- Identify the proposed investigational drug;

- Describe all possible outcomes, including the possibility of unanticipated symptoms and a hastened death, based on the physician's knowledge of the investigational drug and the awareness of the patient's condition;

- Make clear the patient's health insurer and provider are not obligated to pay for care or treatment consequent to the use of the investigational drug;

- Make clear the patient's eligibility for hospice care may be discontinued;

- Make clear the patient's in-home health care may be denied; and

- State the patient is liable for all expenses consequent to the use of the investigational drug and the liability extends to the patient's estate unless other arrangements have been made between the patient and the manufacturer of the investigational drug.

The bill would give the manufacturer of an investigational drug the option of making it available to an eligible patient. A health insurance carrier would have the option of providing coverage for the cost of the investigational drug. An insurer would be allowed to deny coverage to an eligible patient during the use of the investigational drug and for up to six months after usage. An insurer would not be allowed to deny benefits for unrelated pre-existing conditions. The bill states the patient's heirs would not be liable for costs related to the usage of the investigational drug if the patient dies while being treated.

The Board of Healing Arts would not be allowed to revoke, suspend, or otherwise take action against a licensed health care provider based solely on the provider's recommendation that a patient use an investigational drug. Additionally, a physician making a good faith recommendation for usage of an investigational drug would not be subject to criminal or civil liability.

State officers would be prohibited from blocking or attempting to block an eligible patient's access to an investigational drug.

Finally, the bill would state nothing in the bill would be construed as creating a private cause of against a manufacturer or any other person or entity involved with the eligible patient's usage of the investigational drug.

## Background

HB 2004 was introduced by Representatives Hildabrand, Kiegerl, and McPherson. In the House Committee on Health and Human Services, the Representatives testified as proponents of the bill and each noted the long FDA approval process and that drugs are often approved in other countries before the FDA approval process in the U.S. is complete. In addition, Representative Hildabrand discussed personal liberty and humanitarian issues involved with allowing individuals to try treatments not yet approved by the FDA.

A private citizen, diagnosed with a terminal illness, provided testimony in favor of the bill. She shared her personal story and discussed the difficulties with the FDA approval process and the burden of the current expanded access application process. The final proponent was a representative for the Goldwater Institute. He provided information on similar bills in other states.

No opponent testimony was provided.

Neutral testimony was provided by a representative for the Center for Practical Bioethics who focused his testimony on rescue morality, the dangers of allowing risky treatments, and the slippery slope created by the bill with the impact on patients, researchers, and investors. Written only neutral testimony was provided by the Kansas Department of Health and Environment (KDHE) and the Kansas Medical Society (KMS). The KDHE representative stated if Medicaid beneficiaries were allowed to use an investigational drug, federal funding would not be an option as the Centers for Medicare and Medicaid Services does not allow federal funding for drugs and devices not FDA approved. The KMS representative noted the legal uncertainty of the bill, including federal preemption and physician liability, and offered amendments to address some of the concerns.

The House Committee amended the definition of "terminal illness," by deleting the word "disease" and the word "soon," as it relates to the timing of death. The Committee deleted provisions that would have allowed a manufacturer to require eligible patients to pay the costs associated with the manufacture of the investigational drug. The Committee amended the bill to add a definition of "physician," and a provision exempting physicians, who act in good faith, from civil or criminal liability. The Committee deleted references requiring physicians to be consistent with medical standards of care and the exception for a cause of action against a manufacturer, or other entity or person involved in the care of an eligible patient using an investigational drug, for failure to exercise reasonable care. The KMS representative stated there are not medical standards of care related to recommending treatment not approved by the FDA. Finally, technical amendments were made by the Committee at the request of the Office of Revisor of Statutes.

According to the fiscal note prepared by the Division of the Budget on the bill, as introduced, the bill would have a negative fiscal effect on the Board of Healing Arts due to the possibility of increased complaints, investigations, and caseload activity. The Board estimates the enactment of the bill would require an increase of $634,464 in operating expenditures and 8.0 FTE positions; however, the Division of the Budget concludes the Board estimate is excessive and includes more FTE positions and operating expenditures than would be necessary.

The fiscal note indicates the bill would have no fiscal effect on KDHE or the Department of Insurance, although the Department of Insurance states the bill could potentially lead to increased claim costs and increased premiums. Any fiscal effect associated with the bill is not reflected in *The FY 2016 Governor's Budget Report*.